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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-20-1178]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Comprehensive HIV Prevention and Care for Men Who Have Sex with Men of Color to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on August 13, 2019 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of

the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Comprehensive HIV Prevention and Care for Men Who Have Sex with Men of Color (OMB Contrtol No. 0920-1178, Exp. 4/30/2020) - Extension - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Approximately 40,000 people in the United States are newly infected with HIV each year. Gay, bisexual, and other men who have sex with men (MSM) remain the population most affected by HIV infection in the United States (US). Among MSM, those who are black and Hispanic comprise 64% of all new infections. Goals of the National HIV Prevention Strategy and the new initiative "Ending the HIV Epidemic: A Plan for America" include increasing the number of MSM of color living with HIV infection who achieve HIV viral suppression with antiretroviral treatment (ART), and decreasing the number of new HIV infections among MSM of color at risk of acquiring an HIV infection.

Antiretroviral (ARV) medications for pre-exposure prophylaxis (PrEP) can be used for HIV prevention by MSM at substantial risk for HIV acquisition or by those with a possible HIV exposure in the past 72 hours post-exposure prophylaxis (nPEP). The daily use of co-formulated tenofovir disoproxil

fumarate and emtricitabine (marketed as Truvada) for PrEP has been proven to significantly reduce the risk of HIV acquisition among sexually active MSM. In July 2012, the US Food and Drug Administration (FDA) approved an HIV prevention indication for Truvada, and in May 2014 CDC published clinical practice guidelines for provision of PrEP. Given the high incidence of HIV among MSM of color, those who are sexually active are considered at risk for HIV acquisition and thus could benefit from prevention services such as routine and frequent HIV screening with lab-based fourth generation HIV tests, routine screening for STDs, assessment of PrEP eligibility, provision of PrEP (if at substantial risk for HIV acquisition), provision of nPEP (if a possible HIV exposure occurred in the past 72 hours), and/or other risk reduction interventions.

Among people living with HIV (PLWH), ARV treatment can suppress HIV viral load, which both improves health outcomes of individuals and reduces the risk of HIV transmission. Two studies, one that demonstrated the effectiveness of ARV treatment in preventing HIV transmission, and one that demonstrated improved health outcomes for individuals whose ARV treatment was initiated immediately, have led to increased public health focus on interventions and strategies designed to initiate ARV treatment, link, retain, and re-engage PLWH in HIV care, and to provide support for adherence to ARV medications.

The purpose of this project is to support state and local health departments to develop and implement demonstration projects for provision of comprehensive HIV prevention and care services for MSM of color by creating a collaborative with CBOs, clinics and other health care providers, and behavioral health and social services providers in their jurisdiction. Behavioral health services include mental health and substance abuse treatment to enable MSM of color to utilize HIV prevention and care services; social services include services that promote access to housing, job counseling, and employment services to enable MSM of color to utilize HIV prevention and care services.

Comprehensive models of HIV prevention and care for MSM of color will be developed and implemented by a collaborative that is led by the jurisdiction's health department and includes the following: health care providers (e.g., federally qualified health centers (FQHCs), FQHC Look-Alikes, other clinics, or health care providers); HIV care providers (e.g., clinics funded through the Ryan White HIV/AIDS Program (RWHAP clinics), other HIV care clinics, or HIV care providers); behavioral health and social services providers (i.e., mental health and substance abuse services, housing programs, and job training or employment services); and community based organizations (CBOs). Principles of high impact prevention should guide the selection and implementation of activities and strategies to focus on MSM of

color at substantial risk for HIV infection (i.e., eligible for prevention with PrEP), and those living with HIV. MSM of color who are at risk for HIV acquisition but not eligible for or decline PrEP will be provided risk reduction interventions, partner services if diagnosed with an STD, re-testing for HIV and STDs in 3-6 months, and behavioral health and social services. The risk of HIV acquisition should be assessed at every encounter with an individual, and MSM of color at substantial risk of HIV acquisition should be offered PrEP when indicated by the risk assessment.

There are a total of 24 required HIV prevention and care services that must be provided by the health department collaborative for this project, including 13 HIV prevention services for MSM of color at substantial risk for HIV infection and 11 HIV care services for MSM of color living with HIV infection.

HIV prevention services include: 1) HIV testing that uses lab-based 4th generation HIV tests; 2) Assessment of indications for pre-exposure prophylaxis (PrEP) and non-occupational post-exposure prophylaxis (nPEP); 3) Provision of PrEP and nPEP; 4) Adherence interventions for PrEP and nPEP; 5) Immediate linkage to care, ARV treatment, and partner services for those diagnosed with acute HIV infection; 6) Expedient linkage to care, ARV treatment, and partner services for those diagnosed with

established HIV infection; 7) STD screening and treatment; 8) Partner services for patients with STDs; 9) Behavioral risk reduction interventions; 10) Screening for behavioral health and social services needs; 11) Linkage to behavioral health and social services; 12) Navigators to assist utilizing HIV prevention and behavioral health and social services; and 13) Navigators to assist enrollment in a health plan.

HIV care services include: 1) HIV primary care, including antiretroviral (ARV) treatment; 2) Retention interventions; 3) Re-engagement interventions; 4) Adherence interventions; 5) STD screening and treatment; 6) Partner services; 7) Behavioral risk reduction interventions; 8) Screening patients for behavioral health and social services needs; 9) Linkage to behavioral health and social services; 10) Navigators to assist linking to care and accessing behavioral health and social services; and 11) Navigators to assist enrollment in a health plan.

CDC HIV program grantees will collect, enter or upload, and report agency-identifying information, budget data, information on HIV prevention and care services, and client demographic characteristics. The total annual burden hours are 1,534 hours. There are no other costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in Hours)
THRIVE Partners	Monitoring and Evaluation Data Elements on HIV Prevention and Care Services	80	2	9
	Qualitative Interview: Collaborative Process Evaluation	80	1	40/60
	Collaborative Assessment Tool	80	1	20/60
THRIVE Awardees	Monitoring and Evaluation Data Elements on HIV Prevention and Care Services	7	2	1
	Qualitative Interview: Collaborative Process Evaluation	7	1	40/60
	Collaborative Assessment Tool	7	1	20/60
	Funding Allocation Report	7	1	20/60

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